Injury, Int. J. Care Injured 44 (2013) 863–866

Contents lists available at SciVerse ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

The comparison of freehand fluoroscopic guidance and electromagnetic navigation for distal locking of intramedullary implants

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ARTICLE INFO

Article history:
Accepted 6 December 2012

Keywords:
Intramedullary nailing
Fluoroscopy
Electromagnetic guidance

ABSTRACT

Introduction: In locking intramedullary nails, the most important problem is to put the distal interlocking screw accurately and quickly with minimum radiation exposure. The purpose of this clinical study was to compare the fluoroscopic time and surgical time required for distal locking with either free-hand fluoroscopic guidance or with an electromagnetic navigation system.
Materials and methods: The study comprised 54 patients with 58 fractures of the lower extremity. The patients were divided in two groups: distal locking with freehand fluoroscopic guidance (group I) and distal locking with electromagnetic navigation (group II). The primary outcome in this study was fluoroscopy time. The secondary outcome was the operative time in distal interlocking.
Results: In group I, the mean operation time was 108 (81–135) min, the mean time for distal interlocking was 18.35 (9–27) min, the total fluoroscopy time was 47.77 (19–74) s, the mean fluoroscopy time during distal interlocking was 18.29 (2–29) s and the mean attempt at number of distal locking for two screws was 9.96 (2–18) times. In group II, the mean operation time was 80.96 (63–100) min, the mean time for distal interlocking was 7.85 (6.5–10) min, the total fluoroscopy time was 22.59 (15–32) s, the mean fluoroscopy time during distal interlocking was 1.62 (0–2) s and the mean attempt number of distal interlocking was 2 (2–2).
Conclusion: Fluoroscopy time to achieve equivalent precision is significantly reduced with electromagnetism-based surgical navigation compared with free hand fluoroscopic guidance. Also the operative time is significantly reduced with electromagnetic based navigation.

In long-bone fractures, the gold standard of treatment is locking intramedullary nails (IMNs).[1,2] In this method, the most important problem is to put the distal interlocking screw accurately and quickly with minimum radiation exposure.[2] Radiation exposure should be kept as low as reasonably achievable because the long-term effects of exposure to low-level radiation are still largely unknown.[3] Several simplified techniques, tips and pearls of wisdom, jigs, laser-assisted and mechanical guiding instruments, self-guiding and bundle-type nails and surgical navigation systems have been used to perform distal interlocking of IMNs, but none has found widespread acceptance.[4–8] Mechanical aiming systems had been introduced for radiation-independent tibial and femoral nail interlocking, but they were not successful because of failure to take into account the deformation the nail undergoes during insertion into the medullary cavity.[9–12] More recently developed aiming devices, which take nail deformation into account, facilitate distal interlocking with limited exposure to radiation.[6,13,14] Despite the development of sophisticated techniques and devices, the freehand method remains the most commonly used distal interlocking technique.[15–19] The purpose of this prospective clinical study was to compare the fluoroscopy time and surgical time required for distal locking with either freehand fluoroscopic guidance or with an electromagnetic navigation system.

Materials and methods

Study design and patients

The study comprised 54 patients with 58 fractures of the lower extremity. For patient characteristics, see Table 1.

All patients gave informed consent to participate in the study. Thirty-seven fractures were the result of trauma, 19 fractures were the result of gunshot. One patient with a pathological fracture and one patient with revision nailing osteosynthesis for implant failure

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http://dx.doi.org/10.1016/j.injury.2012.12.009

Table 1
Demographic data of the patients.

	Group I $n=31$	Group II $n=27$	P
Age			
Median (range)	36 (15–88)	24 (14–58)	0.032[a]
Sex n (%)			
M	19 (61.3%)	18 (66.7%)	0.78[b]
F	12 (38.7)	9 (33.3%)	
Fracture type			
Closed	23 (59%)	16 (41%)	0.27[b]
Open	8 (42.1%)	11 (57.9%)	
Gustilo 1	2	1	
Gustilo 2	6	8	
Gustilo 3a	–	2	
AO-Class			
32-A	1	1	0.106[b]
32-B	5	2	
32-C	1	1	
42-A	8	8	
42-B	6	3	
42-C	2	1	

[a] Chi-square test.
[b] Mann Whitney U test.

were also included. Closed fractures were classified according to the guidelines of the Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification.[20] Open fractures were classified according to the guidelines of Gustilo–Anderson.[21] Standard inclusion criteria for nailing of femoral and tibial shaft fractures were followed. The exclusion criteria included a bone or soft-tissue infection at the fracture site and a grade 3b or 3c open fracture. A mobile image intensifier (Siremobil 4 N: Siemens, Erlangen, Germany) with continuous-mode fluoroscopy was used.

Surgeons were accepted in three levels, depending on their past experience with different types of IMN: junior resident with <20 applications, senior resident with 20–100 and chief with >100 applications of IMN. All operations were performed by four chief surgeons who had performed >100 IMN.

The guidance method used for distal locking was different in both groups. Patients in group I had distal locking with hands-free fluoroscopic guidance. In group II, distal locking was performed with electromagnetic navigation.

Surgical technique

All IMNs were of the reamed type. Fracture reduction and implant insertion was performed with the patient under general or regional anaesthesia in a standard fashion according to the implant-specific guidelines given by the manufacturer.

Fluoroscopic guidance is used routinely in group I for distal interlocking of the IMNs and the technique is well known. In group II, fluoroscopic guidance is only used at the end of the procedure to confirm the screw position by two shots, antero–posterior (AP) and lateral. We used tibial and femoral IMNs (Sharma IMN, India) in group I, whereas electromagnetic tibial and femoral IMNs were used in group II (spectruM, Sanatmetal; Hungary) (Figs. 1 and 2).

Documentation

For this study, all tibia and femur fractures from February 2011 until April 2012 were included. The data were collected from operative and clinical notes. Recorded data included closed fracture classification according the AO fracture classification system and open fracture classification according the Gustilo–Anderson classification system. The number of attempts and screw misplacement were also recorded. The other measured variables included the duration of distal interlocking of two screws (starting just after the nail is inserted properly and confirmed with fluoroscopy and finishing with inserting two distal locking screws and confirming the final screw position with fluoroscopy), the total surgery time (beginning with the first fluoroscopic image of the extremity, ending with check fluoroscopy to verify correct screw position), the fluoroscopy time during distal interlocking and the fluoroscopy time of total surgery (obtained from the recorded data in the fluoroscopy device).

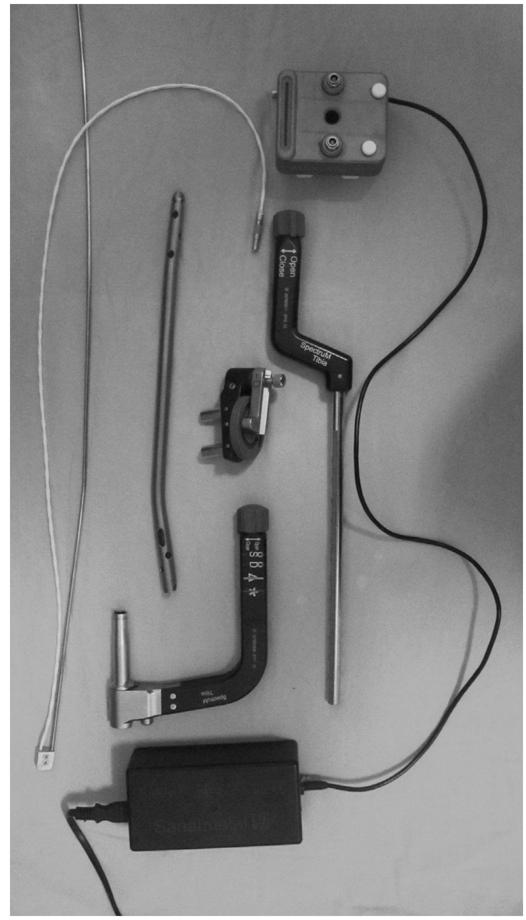

Fig. 1. SpectruM tibial nail.

Fig. 2. Parts of spectruM tibial nail.

Power calculation

Mean operation time was 108 ± 13.51 min in group 1 while it was 80.96 ± 10.85 min in group 2, and there were 31 participants in group 1 and 27 in group 2. If α was accepted as 0.05, power would be 100%. Mean operation time was 96.5 ± 7.63 min in group 1 tibia fractures ($n = 14$) while it was 70.33 ± 7.41 min in group 2 tibia fractures ($n = 9$). If α was accepted as 0.05, power would be 100%. Mean operation time was 117.47 ± 9.17 min in group 1 femur fractures ($n = 17$) while it was 86.27 ± 8.03 min in group 2 femur fractures ($n = 18$). If α was accepted as 0.05, power would be 100%.

Mean fluoroscopy time was 47.77 ± 11.20 s in group 1 while it was 22.59 ± 4.64 s in group 2, and there were 31 participants in group 1 and 27 in group 2. If α was accepted as 0.05, power would be 100%. Mean fluoroscopy time was 46.78 ± 8.39 s in group 1 tibia fractures ($n = 14$) while it was 20.55 ± 3.43 s in group 2 tibia fractures ($n = 9$). If α was accepted as 0.05, power would be 100%. Mean fluoroscopy time was 48.58 ± 13.29 s in group 1 femur fractures ($n = 17$) while it was 23.61 ± 4.91 s in group 2 femur fractures ($n = 18$). If α was accepted as 0.05, power would be 100%.

Statistical analysis

Statistical Package for Social Sciences (SPSS) for Windows version 13.0 was used for statistical analysis. Normality was analysed using the Kolmogorov–Smirnov test. Relationships between nominal variables were calculated using the chi-squared test and median levels between the groups were compared using the Mann–Whitney U test. $P < 0.05$ was considered as significant for all statistical data.

Results

A total of 35 tibia and 23 femur fractures were treated in our clinic. In all cases the technical aspects of the surgical treatment were performed without complications and confirmed by postoperative radiographs. In group I, the mean operation time was 108 (standard deviation (SD) 13.51) min, ranging from 81 to 135 min. The mean time for distal interlocking was 18.35 (SD 3.79) min, ranging from 9 to 27 min. The total fluoroscopy time was 47.77 (SD 11.20) s, ranging from 19 to 74 s. The mean fluoroscopy time during distal interlocking was 18.29 (SD 6.72) s, ranging from 2 to 29 s, and the mean attempted number of distal locking for two screws was 9.96 (SD 3.93) times ranging from 2 to 18 times. In group II, the mean operation time was 80.96 (SD 10.85) min, ranging from 63 to 100 min. The mean time for distal interlocking was 7.85(SD 0.87) min, ranging from 6.5 to 10 min. The total fluoroscopy time was 22.59 (SD 4.6) s, ranging from 15 to 32 s. The mean fluoroscopy time during distal interlocking was 1.62 (SD 0.56) s, ranging from 0 to 2 s. In two nails, distal locking was performed without fluoroscopy. The mean attempted number of distal interlocking was 2 (SD 0); in all nails both of the two distal screws were placed accurately at the first attempt. Comparison of the two groups including both femoral and tibial fractures separately is shown in Table 2.

The fluoroscopy time was statistically significantly shorter in group II compared to group I for both femoral and tibial fractures ($P < 0.001$). In addition, the surgical time was statistically significantly shorter in group II compared to group I for both femoral and tibial fractures ($P < 0.001$).

In group I, there was no statistically significantly difference between the distal locking time in femur and tibia fractures ($P = 0.102$). However, in group II the distal locking time was statistically significantly longer in femur fractures ($P = 0.019$).

Discussion

In this study, we found that the fixation of long bones using the IMNs with electromagnetic guidance had significantly reduced the radiation exposure time to the surgeon and they also reduced the distal locking procedure time. Further, this study had shown that the distal locking procedure with electromagnetic guidance will eliminate the failure rate of the distal locking.

The two main problems in the distal locking procedure are radiation exposure and distal locking failure.[22,23] Nail deformity in the intramedullary cavity could be as large as 4–5 mm. The analysis of numerous data showed that the main distortions take place in different planes at the same time.[9,24] This deformation is the main cause of failure of proximally connected guides in distal locking.[11] Anastopoulos et al. reported 127 patients treated with a distal targeting device with failure in the case of five patients.[25] Suhm et al. reported 39 patients treated with surgical navigation for distal locking of intramedullary implants with one failure (Suhm, Messmer et al., 2004).[26] Boraiah et al. reported 20 patients treated with a distal aiming device with no failure in distal locking.[23] Veen et al. reported 21 cases treated with a distal aiming device in which nine cases needed fluoroscopy when the distal aiming device failed.[18] In this study we had no failure of distal locking with the electromagnetic navigation system. In this system, a flexible sensor is introduced inside the nail which deforms exactly the same way as the nail does. It reads the signals of an electromagnetic source and gives a feedback on the nail position. Further, the sleeves and soft-tissue protectors are threaded and can be locked into the targeting arms.

Radiation exposure to the surgical team as well as to the patient during orthopaedic procedures using fluoroscopic guidance is a

Table 2
Comparison of two groups.

	Group 1 median (range)		Group 2 median (range)		P	
	Femur med. (range)	Tibia med. (range)	Femur med. (range)	Tibia med. (range)	P	P
Age	36(15–88)		24(14–58)		0.032[a]	
	26(15–88)	28.5(15–76)	18.5(14–58)	23(16–49)	0.141	0.231
Operation time (min)	110(81–135)		82(63–100)		0.000	
	118(91–135)	98(81–106)	86(70–100)	71(63–87)	0.000	0.000
Distal locking time (min)	19(9–27)		8 (6.5–10)		0.000	
	21(9–27)	17(14–22)	8(7–10)	7(6.5–9)	0.000	0.000
Total fluoroscopy time (s)	47(19–74)		22(15–32)		0.000	
	48(19–74)	46.5(37–63)	24(15–32)	19(17–26)	0.000	0.000
Distal locking fluoroscopy time (s)	19(2–29)		2 (0–2)		0.000	
	19(2–29)	17.5(12–29)	2(1–2)	1(0–2)	0.000	0.000
Distal locking attempt number	10(2–18)		2(2–2)		0.000	
	12(2–18)	8.5(5–13)	2(2–2)	2(2–2)	0.000	0.000

[a] Chi-square test, Mann Whitney U test.

universal concern. Several studies have evaluated the radiation exposure to orthopaedic surgeons, to the theatre staff and to the patients.[18,27] Kwong et al. stressed the importance of minimising the radiation dose related to fluoroscopic guidance.[28] Despite the concern about radiation exposure and technical difficulties encountered with the placement of distal interlocks, the freehand technique continues to be the most popular technique for placing distal interlocking screws.[4,7] In this study, we compared two guidance methods for distal locking of intramedullary implants. The distal locking procedure was selected as a clinical model to evaluate electromagnetic-based surgical navigation for several reasons. The distal locking procedure is common. Kirousis et al. report that the mean fluoroscopy time is 71(SD 40) s, ranging from 19 to 141 s in the whole intramedullary nailing procedure.[3] Furthermore, Levin et al. report that 60–307 s of fluoroscopy time are required to insert the distal interlocking screws using a freehand method with fluoroscopic guidance.[29] This means that 40–50% of the total fluoroscopic times for nailing are required for the distal locking procedure. In the present study, fluoroscopic times for distal locking with freehand fluoroscopic guidance in group I were found lower than those reported in the literature. Hoffmann et al. reported a cadaver study with comparison of 50 standard freehand fluoroscopic-guided and 50 electromagnetic-guided distal locking procedures. Hoffmann et al. reported a median time benefit of 244 s without using ionising radiation compared with the freehand fluoroscopic technique.[30]

With electromagnetic-based surgical navigation, we succeeded in reducing the fluoroscopic time required to insert two interlocking screws to 1.62 s. In two cases, the distal locking was performed fluoroscopy free.

In the group II, there were no failures. (No screw/drill bit breakage, no screws were placed outside the screw holes and there was no conversion to the freehand technique.) The duration of distal interlocking was reduced by 57.22%. This was statistically significant ($P < 0.001$).

A limitation of this study is the variation in the numbers of femoral and tibial nails in each group. Further, the number of surgeons who performed the operation is another limitation of our study.

Conclusion

In conclusion, this retrospective study on distal locking of intramedullary implants showed that fluoroscopic times to achieve equivalent precision are significantly reduced with electromagnetism-based surgical navigation compared with free-hand fluoroscopic guidance. The ability of the device to correspond to the level of nail deformation and to properly identify the distal holes plays a key role in the production of reliable and predictable results. Further, there is no significant increase in cost compared with the freehand system.

Conflicts of interest statement

None of the authors have a conflict of interest and no financial support was received for this study.

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